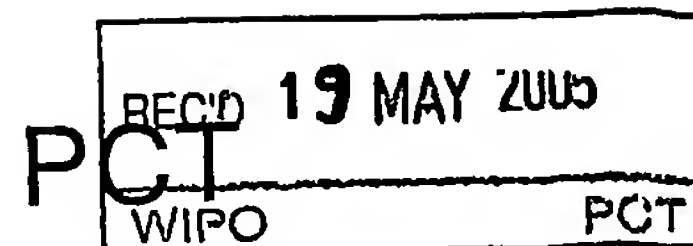


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2005/000337

International filing date (day/month/year)
28.01.2005

Priority date (day/month/year)
30.01.2004

International Patent Classification (IPC) or both national classification and IPC
C11B1/10, B01D61/14, A61K35/56

Applicant
BIONOVATE LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000337

Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000337

**Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or
Industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|-------------|------------|
| Novelty (N) | Yes: Claims | 2-4, 6-7 |
| | No: Claims | 1, 5, 8-11 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 2-4, 6-7 |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Cited references

Reference is made to the following documents:

D1: US-A-5 707 673

D2: WO 97/09992 A

2. Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 5, 8-11 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document): a process for extracting lipids from animal material comprising the steps of a) extracting by means of a solvent, b) filtrating the extract by nanofiltration, followed by c) recycling at least a portion of the separate solvent (cf. abstract and column 4, lines 6-18).

An extractive-rich retentate is thus obtained, which is substantially solvent free (cf. column 3, line 62- column 4, line 5). Thus, the subject matter of claim 1 is not new over D1 (Art. 33(2) PCT).

The additional features of dependent claims 5, 8-11 are also disclosed in D1 (cf. column 2, lines 1-2, column 4, lines 18-22 and column 6, lines 59-61). Thus, claims 5, 8-11 are also not novel over D1.

3. Inventive step

Dependent claims 2-5 are not considered as inventive (Art. 33(3) PCT) for the following reasons.

Document D2, which is considered to represent the closest prior art, discloses a process for extracting lipids from dried, preferably freeze-dried, material from the green-lipped mussel, from which the subject matter claims 2-5 differs in that supercritical fluid extraction is used instead of the solvent extraction process of the present application.

The problem to be solved can thus be seen as providing an improved extraction process, requiring less energy and a reduced amount of equipment.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2005/000337

Such a process, having these advantages is described in D1 for isolating lipids from animal matter. For the skilled man it would therefore have been obvious to combine document D1 and D2 and thus arrive to the teaching of dependent claims 2-5. Dependent claim 6-7 are also not inventive (Art. 33(3) PCT), since the particular characteristics of the nanofiltration membrane are so selected as to permit separation of the lipid material and the solvent.

4. Industrial applicability

The subject matter of claims 1-11 is industrially applicable (Art. 33(4) PCT).